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Inside the secretive but growing world of MDMA-led therapy

Shrouded in controversy, tightly regulated but the science far from settled: inside the veiled world of Australia's legal, cutting-edge, MDMA-led therapy.

By PENNY TIMMS

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Regan Ballantine can feel the drug working less than an hour after swallowing the pill.

Her mind is already shifting. She isn't hallucinating. Rather, she is visualising scenes of metaphorical importance. All seem to provide her with an enhanced perspective about her untapped trauma and how to deal with it.

The first scene shows two old-fashioned movie projectors sitting side-by-side. They play films in unison, with the one on the left representing her son, Wesley, and the one on the right representing her. Then, Wesley's film begins to flicker as if there is a technical error.

Abruptly, Wesley's film stops.

"It represented these two lives living side-by-side, these two stories of a life, and how his just flickered off and mine just kept going," Ballantine says.

"It's such a beautiful metaphor, but there was so much pain around that."

Ballantine's son, Wesley, fell to his death at a construction site in Perth in 2017. His death was found later to have been avoidable. It sent Ballantine into an instant state of shock.

Ballantine estimates it took 18 months just for the shock of Wesley's death to wear off. Picture: Tony McDonough / The Australian

"I went to the building site the day after he died and I didn't shed a tear," she recalls.

"I felt nothing. I didn't even cry at his funeral, I gave a eulogy at my own son's funeral and did not cry. That's disassociation, it's compartmentalising. You do it to survive, because if you feel that part you can't survive."

She estimates it took 18 months just for the shock of Wesley's death to wear off. By then, Ballantine was campaigning to get Western Australia's industrial manslaughter laws changed to hold employers to a higher account for avoidable workplace deaths.

As an advocate, she was smart, calm and composed without being cold; a formula that made her compelling in the eyes of politicians, media and the public. She was someone who commanded attention and respect.

> *"I was tormented by memories of Wesley. Every time something would remind me of him, my breath would leave my body, I'd almost gasp, that's how much of*

> *a state it put me in."*

It was a big responsibility but her resolve was strong and the cut-through she was able to achieve was remarkable.

Her fight for greater justice took years, bringing her before inquiries and into courtrooms.

When all of that finally ended and the courts made their rulings, and the legislation was changed, and the cameras stopped rolling and people stopped looking, Ballantine did something she hadn't done in years: she paused. It was then that the weight of all that responsibility and pent-up emotion came crashing down.

"I just fell into an abyss," Ballantine says. "It was like a lid blew off a pressure cooker.

"Essentially my nervous system was fried, which meant I could not be in the world in the same way. Loud noises, too many people, being too far away from home would all induce anxiety or panic."

It became clear Ballantine had a profound psychological injury from the shock of Wesley's death, the years of reliving it and the fight-or-flight response she had experienced for years. She was diagnosed with complex post-traumatic stress disorder.

Wesley Ballantine was just 17 years old when he fell to his death while working at a construction site.

"I was tormented by memories of Wesley," she says. "Every time something would remind me of him, my breath would leave my body, I'd almost gasp, that's how much of a state it put me in. I couldn't even have photos of him in the house. This emotional derailing would happen multiple times a week."

As Ballantine's PTSD intensified, her world shrank. She avoided any potential triggers but the triggers kept growing so her world kept shrinking. At its worst, she was unable to get out of bed for long stretches of time. Holding down a job seemed like a fantasy.

"It was honestly the most terrifying experience," she says.

"I could no longer control my emotions, and I was in an emotional shutdown response and went into a major depression and could not function. I couldn't get out of bed, couldn't shower, couldn't cook, couldn't leave the house, was having panic attacks. For the first time, I started taking medication."

She tried various therapies but nothing took. She even considered checking into a psychiatric facility. Then she came across an article about MDMA-led therapy and how Australia had become the first country in the world effectively to legalise it as a last-line treatment for PTSD.

Regan Ballantine was suffering severe PTSD when the new treatment became available. Here, she speaks to the experience.

The more she read, the more compelled she became. She discussed it with her medical team and was assessed and approved to receive it at one of the nation's accredited facilities.

In Australia it is legal to use MDMA as a treatment tool for PTSD. Psilocybin, the psychedelic compound found in magic mushrooms, can be used for treatment-resistant depression. However, both drugs must be used only in combination with psychotherapy under tight restrictions and only a selection of trained and approved psychiatrists can prescribe them.

One clinician who oversees MDMA-led therapy in Australia describes the therapies as "the biggest step forward" he has witnessed in his 30-year psychiatry career. That's based on the results he is seeing with patients.

But doubts and concerns remain. Medical groups urge caution, saying there's too much enthusiasm from too little firm evidence. In the void of information, they fear patients could be harmed.

One psychiatrist tells The Australian there are anecdotal accounts suggesting the therapies are only, potentially, slightly more effective than other treatments, though their costs are considerable.

Data to back claims for or against the long-term results of psychedelic therapy, and who may respond well to them and who will not, is scant and still being gathered.

All of this comes while psychedelic-led therapy is growing. Health insurer Medibank Private recently announced it was funding a clinical study into psychedelic therapy.

The Department of Veterans' Affairs has confirmed to The Australian it also will fund MDMA and psilocybin-led therapies under strict clinical conditions for ill veterans.

"Where eligibility requirements are met, veterans will not be required to pay upfront for MDMA and psilocybin-assisted treatment which they have been prescribed," a department spokeswoman says.

"DVA is continuing work to finalise the administrative processes as soon as practicable this year, including necessary governance and safety standards."

Once that happens, the department says it will begin assessing requests for treatment.

Australia's drug regulator also is considering amending the Poisons Standard to allow psilocybin to be used also for people in "existential distress" during end-of-life care. Public submissions on the proposal close in late May.

This is how MDMA is handed to a patient. Picture: Tony McDonough / The Australian

For Ballantine, her experience with psychedelic therapy has been positive and, so far, transformative. But she says it has taken a lot of hard work, reflection and therapy.

"It's not like you take these medicines and it's a passive process where you go on this journey and come out healed," she says. "You get out what you put in."

Welcome to the complicated, messy, secretive and intriguing world of MDMA-led therapy.

A brief history of MDMA

MDMA originally was intended as an appetite suppressant but it attracted little attention and was shelved for decades until it was rebranded as a tool for psychotherapy in the 1970s.

It also became popular for its off-label recreational misuse, which happened to coincide with a cultural uprising and the US war on drugs, leading to the effective global banning of MDMA in 1985 when governments decided it served no medical

purpose and easily could be abused. It was then added to the UN's International Convention on Psychotropic Substances, cementing its status as little more than a party drug.

However, as a Schedule 9 prohibited substance, the drug could be used in limited clinical research, mostly for PTSD though it was tested for other conditions including anxiety, with limited effect.

Its use also has been growing in the fraught underground "wellness" scene. There, unauthorised and self-titled "therapists" have been offering services to paying customers who are desperate for help.

It was a topic canvassed in the 2024 memoir Sassafras by Australian author and researcher Rebecca Huntley, who spoke highly of her experience towards healing from childhood rejection and judgment.

Then there is the much-hyped memoir The Tell by venture capitalist Amy Griffin. The book details the author's experience of underground MDMA "therapy" in the US. It has been a New York Times bestseller, an Oprah Book Club pick and promoted by the likes of the author's high-profile associates including actor and celebrity influencer Gwyneth Paltrow.

However, the story leaves you with a resounding sense that the therapy should be delivered only by somebody with the appropriate training.

But what truly threw MDMA-led therapy into the spotlight was a shock decision in 2023 by Australia's typically conservative drug regulator.

Australia became a global outlier when the Therapeutic Goods Administration went against the advice of medical groups and down-scheduled MDMA to allow it to be used for the treatment of PTSD.

It did the same with psilocybin, allowing it to be used in combination with psychotherapy for treatment-resistant depression. It remains illegal to use either of the drugs recreationally or in an unapproved or non-clinical setting.

In the lead-up to its decision, the TGA considered thousands of submissions as well as the advice of an independent expert panel. The panel noted limitations with clinical data but supported the down-scheduling.

The regulator also was heavily lobbied by Mind Medicine Australia, a non-medical advocate of psychedelic medicine. It is also a registered charity. The group tells The Australian it is now the nation's largest importer of the psychedelic medications.

It is also behind the push to expand the use of psilocybin to the terminally ill.

What is MDMA-led therapy?

MDMA is a drug officially named 3,4-methylenedioxymethamphetamine but is better known by the street names of ecstasy, E, pingers or Molly.

The National Drug and Alcohol Research Centre describes it as a stimulant drug known to increase a person's feelings of empathy, friendliness and social connectedness with others. Street versions sometimes can include other stimulants and hallucinogens.

When used medically in Australia, the pure drug is sourced from a specialist facility in Canada. It arrives under strict security controls and is delivered only to clinics, under guard, shortly before it is provided to the patient. In that briefest of windows between its delivery at a clinic and its use, two clinicians must remain with the medication any time it is not being stored in a bulletproof safe.

The idea of MDMA therapy is that the drug triggers chemical changes in the brain, helping to lower a patient's defences that may otherwise prevent them from delving too deep into their trauma. Once those barriers come down, therapists will try to achieve a new level of counselling.

For patients who do qualify for it, they typically will have three regular therapy sessions in the lead-up to the first dosing session. They will be told what to expect, discuss their treatment goals and develop a working relationship with two therapists – usually a psychologist and a counsellor – who will remain with them for each individual dosing session. There are typically two or three dosing sessions and each will be overseen by a prescribing psychologist also.

A single dosing session lasts between six and eight hours and must be delivered only in a clinical setting under tight security controls and the drug can be administered only by an approved prescriber who has been cleared by regulators. The patient will be offered two doses of the drug across the course of each session, where they will be guided through intensive therapy while under the influence of MDMA.

Then there’s the music.

Michael Winlo, founder and chief scientific officer at Emyria at the Empax Centre in Perth. Picture: Tony McDonough / The Australian

"Music is actually a key part of the therapy," says Michael Winlo, a trained but non-practising doctor and managing director of biotech company Emyria. The company operates several regular clinics and also has been running psychedelic trials and services.

"We have a special service that actually generates a non-repetitive soundscape that is matched to the drug effect. So, we start off with pleasant uplifting music, and then as the drug's peak happens about an hour and a half into the dosing session we will increase the rhythm and intensity of the music. That helps people go into the experience a bit more deeply. And then we bring people out towards the end of the day as well."

He says the sessions often are gruelling.

"We're deliberately trying to confront difficult content that might require revisiting traumatic events or situations or reflecting deeply on broken relationships," he says.

"But what the medication allows is that the sense of fear diminishes. The trust is there, people feel relaxed and open, and finally can talk about that difficult event, situation, circumstance.

"The medicine's there to unlock the power of the therapy."

Dosing sessions are held at least a month apart, with intensive therapy after each. Patients also will experience a comedown effect. They are banned from driving for 48 hours after treatment, must be released into the care of a competent adult and are advised to spend the next few days in a calm environment.

'Music is actually a key part of the therapy,' Winlo. Picture: Tony McDonough / The Australian

For Ballantine, her second dosing session involved the hardest work.

"I described my second dose as doing 10 rounds with Mike Tyson in a cosmic washing machine," she says.

"I was literally traversing the terrain of my subconscious and facing some truths about myself, often hidden truths. That's super challenging."

She says the drug helped her to revisit past events but to consider them from other perspectives, which made it easier to be able to find new ways to confront and deal with them rather than bury them.

One of the other scenes her mind took her to while on MDMA was of a street lined with full garbage bags. The trash represented her grief, fear, anger and rage.

"Because I hadn't dealt with it, it was piled up," she says.

"So, I started taking it out, putting it in the bins. It was about renewal, reprogramming … processing. I started processing the grief and anger. Now I can actually connect to my feelings. This means I can actually take the rubbish out and process my feelings rather than just bury them."

For Ballantine, her second dosing session involved the hardest work. Picture: Tony McDonough / The Australian

The controversy

When drugs are even partially legalised, it can lead to a spike in their recreational use and subsequent harm. MDMA has a well-documented history of harm, including overdose and death.

One of the groups most critical of the TGA's rescheduling decision has been the Royal Australian and New Zealand College of Psychiatrists. It had advised the TGA against the move, saying that while promising evidence was emerging about the role of psychedelics in treatment, the trials were significantly limited and the results still in development.

It urged the TGA to keep the drugs restricted to authorised trials to allow evidence to keep building, but the regulator chose otherwise.

To add salt to the wound, the college then was tasked with developing the industry's clinical guidelines.

"It is a very cautious set of guidelines and that's for good reason," says Richard Harvey, a practising psychiatrist who chaired the college's psychedelic-assisted therapy steering group.

"This is a treatment where we don't have convincing evidence that it's effective. It is an incredibly expensive therapy and we remain very cautious."

Harvey says he has spoken to several clinicians who are delivering psychedelic therapy in Australia and he worries the positives are being over-hyped, instilling unrealistic expectations in patients.

"What I hear, and this is absolutely anecdotal, is that these treatments are almost no different to any other treatment we have in psychiatry," he says. "Typically, 30 to 40 per cent of patients might see some benefit, 30 to 40 per cent of patients experience not much at all and get no benefit, and 30 to 40 per cent of patients experience some sort of adverse experience."

Those anecdotal accounts make him worried, given the treatment's hefty price tag. The cost of MDMA-led therapy sits at about $30,000, putting it out of reach of many people unless they can secure financial support elsewhere or be part of a clinical trial.

Harvey points to the US, where in 2024 the drug regulator rejected legalising MDMA for therapy because, unlike the TGA, it said human trials did not prove MDMA's efficacy and it ruled there was not enough clinical data to outweigh the potential harms of the drug.

"They have raised concerns that we also identified, which is partly around what we call allegiance bias," Harvey says.

"So, the people wanting to do these therapies – the psychiatrists and psychologists – are often very positive about those treatments.

"Patients are often very desperate and have enormous expectations that this is going to be the miracle treatment, partly because of what they read from the people that provide the treatment. It sort of sets up an environment where people can be harmed. And that's not only harm from the medication but harmed financially."

One of the problems with clinical trials for psychedelics is that, even in blind studies, it is apparent to everyone who has taken a mind-altering substance and who has not. That runs the risk of skewing results. The most comprehensive trials also have included intense psychotherapy rather than relying on the drugs alone. Sample sizes and study durations generally have been quite limited also.

Harvey is not vehemently against the therapies but he would like to see more evidence they work, are safe and are worth the significant financial outlay and staffing required to deliver them, especially amid a shortage of mental health workers.

Paul Fitzgerald is head of the Australian National University school of medicine and psychology and is a qualified psychiatrist. His research interests include PTSD and depression as well as psychedelic-assisted psychotherapy.

"I think in some of the trials it looked a little bit better than (the success rate suggested by Harvey). But, given the limitations we have in terms of the trials, I just don't think we really know the results yet," Fitzgerald says.

He is collecting real-world clinical data through a project he is running through ANU, though he says it will take time to develop a clear picture of things.

"One of the very big unanswered questions here is, how much of these treatments is a one-off; do you do the therapy and then it has benefits for years? Or is this something, like most other treatments in psychiatry, where the condition is going to come back again and patients will require further rounds of treatment? That's a really critical but at this stage unanswered question."

It is a question he is working hard to answer.

In March 2025, private health insurer Medibank Private announced it would invest $50m across the next five years into mental health support. A portion of that will

fund a psychotherapy program for eligible patients to analyse their clinical outcomes. Information from that trial will be fed back to the database being run by Fitzgerald.

"We're certainly seeing in the very preliminary analysis that patients are responding to these treatments, having substantial reductions in their PTSD," he says.

"What we don't have yet is the sort of longer-term follow-up to see how long those benefits last. And what we also don't have yet is some of the data we're hoping to get, in terms of the collaboration with Medibank Private, which is how these treatments look in terms of cost effectiveness.

"We need to understand whether that upfront cost pays off over time, including through a reduction in the necessity of other treatments and increasing people's ability to get back into a productive lifestyle."

The support

Supporters point to limited but seemingly encouraging clinical data.

However, these therapies certainly are not for everyone. They are not appropriate for people with certain medical and psychiatric disorders or those taking particular medications. Even patients taking antidepressants will need to wean off their medication before being allowed to take these drugs.

The therapy also is not advised for people who have taken the drugs recreationally.

Many of those working with psychedelics describe the drugs as last-line treatments for people who often are unable to live their lives well and who don't have other options.

Winlo says when the therapies do work, small changes can happen quickly.

"Often, the steps start small because we're dealing with people who've been really severely disabled by their mental health condition, in some cases for many years," he says.

"Patients will turn up the next morning wearing colours for the first time in years. Or say: 'I'm going to cook for myself today', or 'I took out the garbage'.

"These small steps are the building blocks where we help people back into their lives."

While the pool of patients treated with the therapies is still somewhat small, Winlo says his team has tracked the progress of all of them and he is not aware of any who have returned to taking medications to treat their mood disorders.

Jon Laugharne is the lead psychiatrist and medical director at the Empax Centre in Western Australia. Picture: Tony McDonough / The Australian

Jon Laugharne is a psychiatrist based in Perth who oversees MDMA-led therapies alongside Winlo. He is also the group's psychedelics prescriber and says so far the clinic has prescribed MDMA to more than 20 patients.

"Having worked in psychiatry for 30 plus years, this is the biggest step forward that I've seen in my working career," Laugharne says.

"The idea is that it makes the brain very neuroplastic for days, if not weeks, and it creates this opportunity. What we're seeing with patients is new ideas and perspectives, they have new ways of seeing the world and their experiences start to land very quickly in the integration session, sometimes even on the dosing day.

"Some people say: 'I'm finding new rooms in my mind and new doors to walk through that I didn't realise were there.' "

Results from the clinic also are fed back to the national database at ANU. Laugharne says the clinic has data from the first patients treated with the therapies a little more than a year ago and most are continuing to show improvements.

He understands, to an extent, the reservations about psychedelic therapy. But Laugharne argues the regulations in place mean there are plenty of safeguards to protect patients from harm.

"There are always going to be questions," Laugharne says. "There's always going to be potential risks and you always want to minimise those. But what do these patients who are really struggling do in the meantime, while we're waiting for the next study and the next study?"

According to the TGA, there have not been any recorded adverse effects from approved MDMA or psilocybin use since the drugs were down-scheduled.

It has been about eight months since Ballantine received her treatment and she describes herself as being in remission. She also is back at work.

Now, the photographs of Wesley that once were banished painfully from the walls and countertops of her home are back on proud display.

Sure, she still gets triggered. But she says her nervous system is better equipped to cope with those triggers and the challenges life throws at her. She says she also has some new perspectives.

"The anniversary of my son's death is on January 5 and my birthday is on January 6," she says. "So, I'm faced with this situation where I can either have that reaction

for the rest of my life and just be impacted by this rollercoaster of loss and celebration.

"You get to a fork in the road and it becomes a choice of how you see things.

"I'm just so lucky that I get a birthday. That's been a lesson for me; I have the gift of life. When you lose a life like that, in a heartbeat, you understand the sanctity of it. I honour my son by honouring my own life and living my life well."

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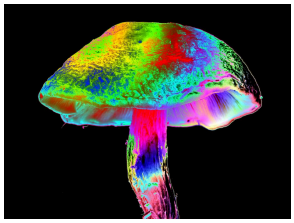

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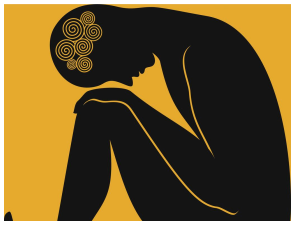

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